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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,891	07/17/2003	Graham Alan March	GAM 6410.1	2751

321 7590 04/12/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/622,891	MARCH, GRAHAM ALAN	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *33-62* is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/21/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-62 are pending in this application.

Election/Restrictions

Claims 33-62 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant's election with traverse of invention Group I, drawn to a pharmaceutical composition comprising sodium 4-phenylbutyrate, an effective amount of aromatic flavoring agent, and an effective amount of synthetic sweetening agent claims 1-32 in reply filed on 01/11/2007 is herein acknowledged. Applicant argues that the examination of Groups I, II, and III may be made without serious burden. This argument has been considered, but not found persuasive because although the search for the inventions is overlapping, the search for the invention of the 3 groups would not be coextensive because a search indicating that the method is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the method is known or would have been obvious. Therefore, restriction for examination purposes as indicated is proper, and herein made final.

Claims 1-32 are examined herein on the merits as they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 1, 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "aromatic flavoring agent" in the claims is vague and indefinite, as it is not clear what compounds this term encompasses, and since one of ordinary skill in the art could not ascertain the metes and bounds as to "aromatic flavoring agent", and the specification does not provide any information with respect to the term "aromatic". It is not clear if the applicant intends to mean a flavoring agent having aromatic structure i.e containing benzene ring or a substance with fragrant aroma.

2) Claims 10, 13-17, 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "effective amounts being selected so as to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate" in claims 10, 20-22 and "the effective amounts being selected so as to mask substantially the bitter taste following dilution" in claim 13 render the claims indefinite. The recitation "effective amounts being selected so as to mask substantially the bitter taste" is not defined in claim, and the specification does not provide information as to the amount that masks the bitter taste, and it is not clear what amounts of sweetening agent, and flavoring agents would mask the bitter taste substantially. It is not clear as to what the applicant intends to convey by the recitation "to mask substantially the bitter taste and pungent odor", is it completely

i.e 100 % free of bitter paste and pungent odor or 99.6 % etc. free of bitter paste and pungent odor, and it is not clear as to the amounts of sweetening agent, and flavoring agents that are needed to mask the bitter taste completely or by 99.6 % etc.

3) Claims 13-17, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "up the solubility limit thereof measured at 10 °C" in claim 13 is vague. It is not clear what the applicant means by this recitation.

4) Claims 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "binding amount of a binding agent" in claim 23 render the claims vague, and indefinite. The recitation "binding amount of a binding agent" is not defined in claim, and the specification does not provide information as to how much is the binding amount of a binding agent that can be used in the instant composition.

5) Claims 23-28 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sufficient" in line 9, claim 23 is vague because it is subjective.

Claims 23, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "artificial water soluble sweetening agent" in the claim. Claim 31 recites the limitation "one synthetic water soluble softening agent" in the claim There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samid et al. (6,037,376, PTO-892), in view of Rubenstain et al. (US 2002/0115619, PTO-892), and further in view of Blase et al. (US 5,272,137, PTO-892).

Samid et al. discloses pharmaceutical compositions comprising sodium phenylbutyrate, a water soluble sweetening agent, sugar, and a binder, Sterotex. See column 25-26, EXAMPLE 18, EXAMPLE 21, and EXAMPLE 21.

Samid et al. do not explicitly teach an aromatic flavoring agent.

Samid et al. do not teach the employment of the particular synthetic sweetening agents aspartame and potassium acesulfame.

Rubenstain et al. (US 2002/0115619, PTO-892) teach that sodium 4-phenylbutyrate has bad taste in the mouth. See page 13, paragraph [0143]. Rubenstain et al. teaches that compositions in the form of Tablet therein can contain sweetening

agent, a flavoring agent, or some combinations thereof in order to provide pharmaceutically elegant and palatable preparation. See page 8, paragraphs [0097]-[0105]; paragraph [0112].

Blase et al. teaches taste masked pharmaceutical compositions. It is taught that artificial sweeteners, and fruit flavoring agents are employed in the pharmaceutical compositions to mask the disagreeable taste of the pharmaceutically active agent. See abstract; column 1, lines 6-10; 62-68; column 4, lines 29-34, line 55-column 4, line 6, column 5. It is disclosed that artificial sweeteners such as aspartame, acesulfame potassium, saccharin, sucrolose or mixtures, and fruit flavors such as cherry, grape, orange, strawberry or lemon are employed. It is also taught that the amount of artificial sweetener used in the pharmaceutical composition therein can be upto 5 grams per 100 mL of suspension. The amount flavoring agent can be present in an amount upto 5 grams per 100 mL of the suspension. See line 55-column 4, line 6, column 5; column 10, claims 1, 4.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ aromatic flavoring agents, and specific synthetic sweetening agents aspartame and potassium acesulfame in the compositions comprising sodium 4-phenylbutyrate taught by Samid et al. because 1) Rubenstain et al. teach that sodium 4-phenylbutyrate has a bad taste, and also teaches that the compositions comprising sodium 4-phenylbutyrate can contain flavoring agents, and artificial sweetening agents, and 2) Blasé et al. teach that aspartame, acesulfame potassium, saccharin, sucrolose or mixtures, and fruit flavors such as cherry, grape, orange, strawberry or lemon are

employed in pharmaceutical compositions to mask the disagreeable taste of the pharmaceutically active agent. Thus, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

Furthermore, as the combined teachings of Samid et al., Rubenstein et al., Blase et al. renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claim 10 are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstain et al. (US 2002/0115619, PTO-892), in view of Blase et al. (US 5,272,137, PTO-892).

Rubenstein et al. discloses a pharmaceutical composition comprising sodium 4-phenylbutyrate. See page 2, paragraph [0019], [0022]; page 11, [0122]; page 13, [0143]. It is also taught that the pharmaceutical compositions therein can be in the form of a tablet, a soft capsule, a chachet, a troche, or a lozenge. The formulations for oral administration include, a powdered or granular formulation, an aqueous or oily suspension, an aqueous or oily solution or emulsion. The compositions therein can contain binding agents such as polyvinylpyrrolidone, hydroxypropyl methylcellulose. The compositions comprise from 0.1 % to 100 % (w/w) active ingredient. Page 8, paragraph [0094]. It is also disclosed that sodium 4-phenylbutyrate has bad taste in the mouth. See page 13, paragraph [0143]. The compositions in the form of Tablet therein can contain sweetening agent, a flavoring agent, or some combinations thereof in order to provide pharmaceutically elegant and palatable preparation. Sweetening agents include glycerol, propylene glycol, sorbitol, sucrose, and saccharin i.e a synthetic sweetening agent. See page 8, paragraphs [0097]-[0105]; paragraph [0112]. It is also taught that the pharmaceutical compositions therein can be in a single or multi unit-dose. See page 8, paragraph [0090].

Rubenstein et al. do not explicitly teach an aromatic flavoring agent.

Rubenstein et al. do not teach the employment of the particular synthetic sweetening agents aspartame and potassium acesulfame.

Rubenstein does not specifically teach the particular amounts of flavoring agents, sweetening agents, and binding agent in the composition therein.

Blase et al. teaches taste masked pharmaceutical compositions. It is taught that artificial sweeteners, and fruit flavoring agents are employed in the pharmaceutical compositions to mask the disagreeable taste of the pharmaceutically active agent. See abstract; column 1, lines 6-10; 62-68; column 4, lines 29-34, line 55-column 4, line 6, column 5. It is disclosed that artificial sweeteners such as aspartame, acesulfame potassium, saccharin, sucrolose or mixtures, and fruit flavors such as cherry, grape, orange, strawberry or lemon are employed. It is also taught that the amount of artificial sweetener used in the composition therein can be upto 5 grams per 100 mL of suspension. The amount of flavoring agent can be present in an amount upto 5 grams per 100 mL of the suspension. See line 55-column 4, line 6, column 5; column 10, claims 1, 4.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ aromatic flavoring agents, and specific synthetic sweetening agents aspartame and potassium acesulfame in the compositions comprising sodium 4-phenylbutyrate because 1) Rubenstein et al. teach that sodium 4-phenylbutyrate has a bad taste, and also teaches that the compositions comprising sodium 4-phenylbutyrate can contain flavoring agents, and artificial sweetening agents, and 2) Blase et al. teach that aspartame, acesulfame potassium, saccharin, sucrolose or mixtures in amount upto 5 grams per 100 mL of composition, and fruit flavors such as cherry, grape, orange, strawberry or lemon in an amount upto 5 grams per 100 mL of the composition are

employed in pharmaceutical compositions to mask the disagreeable taste of the pharmaceutically active agent . Thus, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as amounts of flavoring agents, sweetening agents, and binding agent employed in the composition of Rubenstein et al., to obtain a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the amounts of flavoring agents, sweetening agents, and binding agent employed in the compositions, since Blase et al. teach such amounts of flavoring agents, sweetening agents, and further the optimization of amounts of known agents in a composition, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Furthermore, as the combined teachings of Rubenstein et al., Blase et al. renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claims 10, 13, 20, 22 are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

It is pointed out that the recitation "the unit dose prepared by diluting with water an aliquot of a concentrated aqueous solution containing at atleast about 200 mg/ml of up the solubility limit thereof measured at 10 °C" in instant claim 20, and "wherein the granules are mixed with the at least one synthetic water soluble softening agent and with at least one water soluble flavoring agent to form the wetted mass" in claim 31, are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art the claim is unpatentable even though the prior product was made by a

different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 ('Fed. Cir. 1985). See MPEP 21 13.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER